REMARKS

The pending Office Action addresses claims 1-40, rejecting claims 1, 3, 7, 8, 10, 11, 14-20, 22, 25, and 28-40. Claims 2, 4-6, 9, 12, 13, 18, 23, 24, and 27 are withdrawn from consideration for being directed to a non-elected species of the invention. By this amendment, independent claims 29 and 40 are amended to recite an "***implantable*** drug release assembly" "***implantable*** controlled release drug device," respectively, in order to better characterize the present invention. Support for this limitation can be found throughout the specification, and specifically at page 4, lines 16-26, which states that the controlled release delivery unit can be implanted. Claim 29 is additionally amended to recite that the infusion pump assembly is effective to convey a fluid within the pump through a fluid delivery line ***to a discharge portion positionable at a target tissue site.*** Support for this limitation can be found in original claim 1. Accordingly, no new matter is added by these amendments. For all of the following reasons, Applicants respectfully request reconsideration of the present application in view of the current amendments.

The Prior Art Rejections

The Examiner rejects claims 1, 3, 10, 11, 14-17, 19, 20, 22, and 28-40 under 35 U.S.C. §102(b) as being anticipated by either U.S. Patent No. 6,966,218 to Flaherty et al. or U.S. Patent No. 6,669,682 to Gibson et al. In addition, the Examiner rejects claims 1, 3, 7, 8, 10, 11, 14-17, 19, 20, 22, 25, and 28-40 as being anticipated by U.S. Patent No. 5,989,445 to Wise et al., while claims 1, 3, 10, 11, and 29 are rejected as being anticipated by U.S. Patent No. 4,193,397 to Tucker et al. Finally, claims 1 and 29-40 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Publication No. 2002/0082583 to Lerner. For the following reasons, Applicants respectfully request reconsideration and withdrawal of each one of these rejections.

Applicants' Invention

Applicants' invention is directed to an implantable drug delivery system that enables an effective amount of a desired drug to be delivered to the target treatment site, without substantially diminishing the concentration of the drug during the delivery process. To accomplish this goal, the delivery system includes a fluid delivery pathway or line that extends from an implantable drug reservoir to a discharge portion that is positionable in the immediate

vicinity of the target site. When a drug is released from the reservoir, it travels to the target site via the delivery line without substantial dilution (i.e., since the drug does not travel to the target tissue region by diffusion, the treatment concentration of the drug can be maintained). As described in Applicants' specification, this delivery pathway or line can take the form of, for example, an implantable conduit, catheter, or tube. (*See,* page 4, lines 28-32; page 5, lines 19-22; page 8, lines 4-8). These key concepts are reflected in each of the independent claims (claims 1, 29 and 40), and are discussed in greater detail below.

Independent claim 1 requires an implantable drug delivery system comprising a fluid delivery line extending from an infusion pump and being in communication with a controlled release drug assembly for discharging drug material at a target tissue site. As amended, independent claim 29 now requires an infusion pump assembly, an implantable drug release assembly, and a fluid delivery line in communication with the infusion pump and drug release assembly for transporting drug material to a discharge portion positionable at a target tissue site. Finally, amended independent claim 40 now requires an infusion pump assembly in communication with an implantable delivery line and implantable controlled release drug device for the delivery of drug material to a target tissue site.

The Prior Art

Contrary to the Examiner's assertions, none of the cited references anticipate the claimed invention. In the following remarks, Applicants address the deficiencies in each of the cited references in the order in which the references appear in the Office Action.

U.S. Patent No. 6,699,218 to Flaherty et al.

The '218 patent to Flaherty et al. fails to satisfy the claimed invention because the drug delivery devices disclosed are not implantable. As illustrated in the drawings and as described at column 8, lines 7-19 and column 13, lines 31-47, the drug delivery devices of Flaherty et al. have a delivery cannula with a sharpened distal end for penetration through a patient's skin and insertion into the subcutaneous tissue. The rest of the delivery cannula and the drug release assembly, however, remains external to the patient. In fact, as shown in FIGS. 15-17, 19, and 21, the drug release assembly stays on the patient's skin surface so that the only portion of the

drug delivery device which extends into the patient is the distal end of the delivery cannula. Hence, and as the title of the patent "*Transcutaneous* Delivery Means" suggests, the delivery devices of the '218 patent enable drug material to be delivered through skin. In no way, however, are the delivery devices implantable within the patient, as required of the claimed invention. Accordingly, the '218 patent to Flaherty et al. fails to meet each and every limitation of the claimed invention and therefore does not anticipate Applicants' invention.

U.S. Patent No. 6,669,682 to Gibson et al.

Similar to the previous patent, the '682 patent to Gibson et al. also does not anticipate the claimed invention because the patent fails to disclose an implantable drug delivery assembly. Instead, Gibson et al. discloses a drug delivery device (1) having a transdermal skin patch (11) for the delivery of therapeutic agents through the skin or hide of an animal (see column 9, lines 48-53) and a delivery conduit (9) whose distal end is insertable into a vaginal cavity of a cow for delivery of drug material therein (see column 9, line 18-27). As clearly shown in FIG. 1 and as described at column 8, lines 30-34, "the device (1) is secured to the outside of the cow by attachment to a strap (3) of a harness." The drug release assembly (1) and the majority of the delivery conduit (9), therefore, remains external to the cow and is thus not implantable, as specifically required of the claimed invention. Accordingly, the '682 patent to Gibson et al. fails to meet each and every limitation of the claimed invention and therefore does not anticipate Applicants' invention.

U.S. Patent No. 5,989,445 to Wise et al.

The '445 patent to Wise et al. discloses a microchannel probe for the delivery of chemical agents to local volumes of tissue. Although the probe (70) is illustrated in FIGS. 5-7, there is no drawing or discussion of the probe (70) relative to the intended tissue area to be treated. In fact, the '445 patent fails to disclose or suggest how, if at all, the probe (70) is implantable. Further, there is no disclosure of an infusion pump or a controlled release drug assembly in connection with the microchannel probe for controllably releasing the drug material to the target tissue site, both of which are required of the claimed invention. Since the '445 patent to Wise et al. fails to disclose each and every limitation of the claimed invention, this reference does not anticipate Applicants' invention.

U.S. Patent No. 4,193,397 to Tucker et al.

The '397 patent to Tucker et al. discloses an implantable infusion apparatus for delivering a fluid such as insulin to a selected site in a patient. The infusion apparatus of Tucker et al., as shown in FIGS. 2-4, includes a tubine (92) for releasing the fluid into the patient. Independent claims 1 and 29 require that the fluid delivery line extend from the fluid outlet to a discharge portion *positionable at a target tissue site*. There is no such disclosure or suggestion in the '397 patent of this limitation. That is, there is no fluid delivery line that extends from the fluid outlet (92) to a discharge portion that is positionable at a target tissue site. Accordingly, the '397 patent fails to meet each and every limitation of the claimed invention, and therefore does not anticipate Applicants' invention.

U.S. Patent Publication No. 2002/0082583 to Lerner

The Lerner publication discloses a delivery device for controlled delivery of a therapeutic agent into spinal structures and/or the brain of a patient. As shown in the drawings and as described at paragraphs [0050] and [0056], the therapeutic agent is to be incorporated into a polymer matrix for dilution at the target site via a coating on an expandable balloon. At paragraph [0052], Lerner teaches away from free fluid delivery, citing the risk of leakage and the ability to eliminate additional catheter lumens as reasons for using instead drug-laden polymer coatings or microspheres. For this reason, Lerner does not disclose an infusion pump or a *fluid* delivery line extending from the infusion pump to a discharge portion positionable at a target tissue site, as is required of the claimed invention. Accordingly, the Lerner publication fails to anticipate Applicants' invention.

In conclusion, all of the above references suffer from deficiencies that prevent them from satisfying each and every limitation of the claimed invention. Because of these aforementioned deficiencies, none of the references cited in the present Office Action anticipates the presently claimed invention.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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